

## **Remarks**

Claims 1-4 and 8-27 are pending in this application. Applicants note with appreciation the allowance of claims 1-3, 12-14, 17 and 18. Claims 4, 8-11, 15-16 and 19-27 have been rejected.

Claims 16 has been cancelled. Claims 4, 8, 9-10, 19 and 25 have been amended.

### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claim 10 and 11 stand rejected under 35 U.S.C. §112, second paragraph. Applicants have amended claim 10 to overcome the rejections.

### **Rejections under 35 U.S.C. § 102**

Claims 4, 9-11, 15, 16 and 19-27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Monson (U.S. Patent No. 4,863,477).

#### **Independent Claim 4**

Claim 4 has been amended to include the novel features of “prior to forming the concave, non cylindrical surfaces in the vertebral body endplates, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and fixing a bone surface milling mechanism to the at least one anchor.”

Claim 12, which has already been allowed, also includes similar features. Therefore, claim 4 should be allowed.

#### **Independent Claim 9**

Claim 9 has been amended to include the novel features of “prior to forming the dome-shaped, concave surfaces in the adjacent spinal vertebral bodies, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and affixing a bone surface milling mechanism to the at least one anchor.”

Claim 12, which has already been allowed, also includes similar features. Therefore, claim 9 should be allowed.

#### Independent Claim 19

Claim 19 has been amended to include the novel features of “(c) prior to forming the concave surfaces in the vertebral body endplates, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body, and (d) affixing a bone surface milling mechanism to the at least one anchor.”

Claim 12, which has already been allowed, also includes similar features. Therefore, claim 19 should be allowed.

#### Independent Claim 25

Claim 25 has been amended to include the novel features of “prior to forming at least the portion of the hemispherical cavity in the endplate of one of the vertebral bodies, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and affixing a bone surface milling mechanism to the at least one anchor.”

Claim 12, which has already been allowed, also includes similar features. Therefore, claim 25 should be allowed.

#### Dependent Claims

Claims 10-11, 15, 20-24 and 26-27 depend on and further limit independent claims 4, 9 and 25, and should also be allowed.

#### Rejections under 35 U.S.C. §103

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Shepperd (U.S. Patent No. 4,863,476) in view of Michelson (U.S. Patent No. 5,015,247).

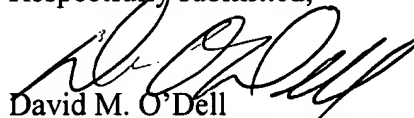
Claims 8 has been amended to include “implanting at least one anchor into one of the mounting holes; utilizing the at least one anchor to mount a bone mill on the patient’s spine[.]”

Claim 12, which has already been allowed, also includes similar features. Accordingly, claim 8 should be allowed.

**Conclusion**

Applicants respectfully submit that all the claims in this application are in condition for allowance. The Examiner is invited to contact the undersigned at the numbers provided below if further consideration is required. Also, Deposit Account No. 08-1394 may be used for any over or under payments.

Respectfully submitted,



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R-48278\_1.DOC

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Box 1450 RCE, Washington, D.C. 20231 Alexandria, VA 22313 on <u>6-2-03</u> <u>BE Boyle</u>
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**Claim Amendments As Compared to  
The Previously-Filed Amendment**

4. (Amended Four Times) A method of surgery comprising:  
forming concave, non cylindrical surfaces in the endplates of confronting vertebral bodies[, and];  
inserting between the formed concave surfaces an intervertebral disc endoprosthesis including:  
confronting supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces[.]; and  
a resilient body interposed between the supports[.];  
prior to forming the concave, non cylindrical surfaces in the vertebral body endplates, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and  
affixing a bone surface milling mechanism to the at least one anchor.
8. (Amended Twice) A method of spinal surgery comprising:  
forming mounting holes in one or more vertebral bodies of a patient's spine;  
implanting at least one anchor into one of the mounting holes;  
utilizing [said mounting holes] the at least one anchor to mount a bone mill on the patient's spine;  
milling confronting bone surfaces on and in the patient's spine to a predetermined surface shape;  
removing said mill; and  
mounting an intervertebral disc endoprosthesis having a predetermined outer surface shape so that outer surfaces of the intervertebral disc endoprosthesis mate with the previously milled bone surfaces and are capable of motion relative to each other.

9. (Amended Four Times) A method of endoprosthetic discectomy surgery comprising:

- receiving information about the size, shape, and nature of a patient's involved natural spinal vertebral bodies and natural spinal vertebral discs from imaging devices[.];
- removing at least the involved, damaged natural spinal disc material from the patient's spine[.];
- forming dome-shaped, concave surfaces in adjacent spinal vertebral bodies[, and];
- implanting into the patient's spine, an intervertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements that at least partly surround and are capable of movement relative to the resilient disc body in the patient's spine[.];
- prior to forming the dome-shaped, concave surfaces in the adjacent spinal vertebral bodies, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and
- affixing a bone surface milling mechanism to the at least one anchor.

10. (Amended) The method of surgery accordingly to claim 4, further comprising affixing the [concaval-convex] supports to the adjacent bone of the vertebral body.

19. (Amended Twice) A method of surgery comprising:

- (a) forming concave surfaces in the endplates of confronting vertebral bodies,[ and ]
- (b) inserting between the formed concave surfaces an intervertebral disc endoprosthesis, comprising:
  - (1) confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces,
  - (2) a resilient body interposed between the concaval-convex supports, and comprising a gasket and nucleus[.],
- (c) prior to forming the concave surfaces in the vertebral body endplates, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body, and

(d) affixing a bone surface milling mechanism to the at least one anchor.

25. (Amended) A method of inserting a prosthesis in a disc space between two adjacent vertebral bodies, comprising:

forming at least a portion of a hemispherical cavity in an endplate of one of the vertebral bodies, the endplate have a remaining surface surrounding the cavity[, and];

inserting an endoprosthesis into the disc space and the cavity, the endoprosthesis including at least one support having an exterior convex surface adapted to mate with the cavity, and a body interposed between the at least one support and the second vertebral body, where the at least one support is movable relative to the body[.];

prior to forming at least the portion of the hemispherical cavity in the endplate of one of the vertebral bodies, implanting at least one anchor into a hole having a predetermined position in an anterior surface of at least one adjacent vertebral body; and

affixing a bone surface milling mechanism to the at least one anchor.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/776,394

02/02/2001

Vincent Bryan

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04/15/2003

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EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/15/2003

RECEIVED

APR 22 2003

HAYNES & BOONE, LLP  
RICHARDSON



Please find below and/or attached an Office communication concerning this application or proceeding.

6/15/03 - response due to  
promote advisory action  
10/15/03 - DD Notice of Appeal  
due

Docketed 4.21.03

By cal  
JAL

**Office Action Summary**

JUN 05 2003

Application No.

09/776,394

Applicant(s)

BRYAN ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 12-14, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 4, 8-11, 15, 16 and 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_



## DETAILED ACTION

### *Request for Continued Examination*

The request filed on January 02, 2003 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/776,394 is acceptable and a RCE has been established. An action on the RCE follows.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the concaval-convex supports" in lines 1 & 2. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 9-11, 15, 16 and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monson US Patent 4,863,477

Monson discloses an intervertebral implant comprising two supports (4 & 6) having a convex shape (see col. 2, lines 55-63) adapted to mate with concave non-cylindrical

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surfaces on vertebral bodies and a resilient body (30 and 42) interposed between the supports such that the supports are capable of movement relative to the resilient body. Finally, the resilient body has a gasket (ridges (32, 33, 34, 35, 36 and 38)) and a nucleus (mid-section of elements (30 and 42)).

Regarding the phrase "forming concave, non cylindrical surfaces...", the Monson reference does not clearly disclose a concave non cylindrical surfaces at the endplates of the confronting vertebral bodies. However, Monson discloses an implant having a non-cylindrical shape (see Figures 1 & 2). Therefore, in order to insert the non-cylindrical implant and creates a good frictional adhesion with the inner surface of the confronting vertebral bodies (see col. 2, lines 59-63), the above confronting vertebral bodies have to have a non-cylindrical shape.

Regarding claim 9, see col. 1, lines 58-61; col. 5, lines 19-21.

Regarding claim 10 and 11, see col. 2, lines 55-63.

Regarding claim 15, see col. 5, lines 30-35.

Regarding claim 16, the ridges (32, 33, 34, 35, 36 and 38) surrounding the resilient body (30 & 42) comprise the fluid-tight seal member (see col. 1, lines 63-66).

Regarding the last three lines of claim 9, the Shepperd reference discloses the abutment of the outer surface of the spinal implant with the surface of the vertebral bones (see col. 1, lines 64-68). Additionally, Shepperd reference teaches a rockable spinal disc (see col. 4, lines 1-8).

Finally, if the vertebral bones have a concave shape then the shape can be interpreted as a dome.

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*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepperd US Patent 4,863,476 in view of Michelson US Patent 5,015,247.

Shepperd discloses an implant having two supports (5 & 6) with a convex outer shape and capable of motion relative to each other (see col. 4, lines 1-8). Shepperd discloses a small incision in the skin and the cartilage that can be made by the Michelson method. The implant has all the structural limitations in order to be used on the Michelson reference.

Michelson teaches a method of inserting a cylindrical implant between the vertebral bodies. Michelson discloses the steps of: forming mounting holes in vertebral bodies by spikes (see Figs. 1-3), using those holes to mount a bone mill on the spine (see figs. 3 and 4), removing the mill, mounting an intervertebral disc (see Fig. 4) that mate with the vertebral bone walls (see Figs. 4d and 5).

Therefore, for the above reason, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implanting method of the Michelson reference in order to implant the Shepperd prosthesis between two vertebral bodies for the purpose of increasing the implanting speed and reduce injury to other part of the body.

*Response to Arguments*

Applicant's arguments filed January 02, 2003 have been fully considered but they are not persuasive.

Regarding claims 4, 10, 11, 15, 16 and 19, the phrase "forming concave, non cylindrical surfaces...", in the Monson reference does not clearly disclose a concave non cylindrical surfaces at the endplates of the confronting vertebral bodies. However, Monson discloses an implant having a non-cylindrical shape (see Figures 1 & 2). Therefore, in order to insert the non-cylindrical implant and creates a good frictional adhesion with the inner surface of the confronting vertebral bodies (see col. 2, lines 59-63), the above confronting vertebral bodies have to have a non-cylindrical shape.

Regarding claim 8, the Applicant's representative is focusing on the term "small incision" and the Examiner wants to remind to the Applicant's representative that the term "small incision" is not defined in the Applicant's specification and/or the claims. However, the incision made to a patient in order to replace an intervertebral disc is a lot smaller compare to an incision made in an open-heart surgery. Therefore, the incision made during the Monson reference, the Sheppard reference and the Michelson reference are a lot smaller than the incision during an open-heart surgery.

Sheppard is partially silent regarding the used of inserting tools. Sheppard discloses in Figures 6 and 8 an insertion tool but does not disclose a mill and the step of forming mounting holes. Additionally, Sheppard discloses that the spinal disc is inserted in the joint space between two adjacent vertebrae and the outer surface of the spinal implant is made of morous titanium material in order to abut with the surface of the vertebral bones (see col. 1, lines 64-68; and col.

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2, lines 45-48). Therefore, if the outer surface of the spinal disc abuts the vertebral bones surfaces, then the surgeon needs an instrument in order to remove the all or parts of the natural disc. The only reason the Examiner used the Michelson reference was to modify the distal end of the delivery system of the Shepperd reference with the sharp distal end and the bone mill of the Michelson et al reference in order to creates the mounting holes and remote tissue material from the intervertebral spaces by the bone mill.

Finally, the Shepperd spinal disc is capable of been used by the insertion tools of the Michelson reference.

*Allowable Subject Matter*

Claims 1-3, 12-14, 17 and 18 are allowed.

*Conclusion*

This is a RCE of applicant's earlier Application No. 09/776,394. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
AST  
April 8, 2003

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700